COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28-IV-2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 28-IV-2004

granting the marketing authorization for the orphan medicinal product for human use "Lysodren - Mitotane" under Council Regulation (EEC) No 2309/93

ONLY THE FRENCH TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[3],

Having regard to the application submitted by Laboratoire HRA Pharma, on 18 November 2002, under Article 4(1) of Regulation (EEC) No 2309/93,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 21 January 2004,

Whereas:

(1) Commission Decision C(2002)2228 of 12 June 2002 designated "Mitotane" as an orphan medicinal product.

(2) The orphan medicinal product "Lysodren - Mitotane" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4] as amended by Directive 2002/98/EC[5] and by Directive 2003/63/EC[6].

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 18, 22.1.2000, p. 1.
[4] OJ L 311, 28.11.2001, p. 67.
[5] OJ L 33, 8.2.2003, p. 30.
[6] OJ L 159, 27.6.2003, p. 46.

(3) It is therefore appropriate to authorise its placing on the market.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted for the orphan medicinal product "Lysodren - Mitotane", whose characteristics are summarised in Annex I hereto. This orphan medicinal product is registered in the Community register of medicinal products under Nos:

EU/1/04/273/001 Lysodren - 500 mg - Tablet - Oral use - Bottle (HDPE) (glass) - 100 tablets

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the orphan medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to Laboratoire HRA Pharma, 19, rue Frédérick Lemaitre, F-75020 Paris, FRANCE.

Done at Brussels, 28-IV-2004

For the Commission
Erkki LIIKANEN
Member of the Commission